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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,573	03/25/2004	Arkady Glukhovsky	P-5812-US	5075
49443	7590	09/01/2006	EXAMINER	
PEARL COHEN ZEDEK, LLP 1500 BROADWAY 12TH FLOOR NEW YORK, NY 10036			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 09/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/808,573

Applicant(s)

GLUKHOVSKY, ARKADY

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 37-51 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 37-51 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 103***

2. Claims 37-39, 41-46, 49, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rich'816 (US Patent Application Publication 2002/0151816) in view of Kilcoyne'138 (US Patent Application Publication 2004/0158138).

Regarding claim 37, Rich'816 discloses a method of determining a direction of flow through a patient's tract (paragraphs [0050] and [0083]) comprising inserting sensors separated by a distance within the tract (elements 12, figure 19); sampling the output of the sensors over time (paragraph [0071]); determining a gradient between the output of the sensors over time (paragraph [0089]); and determining the direction of flow over the distance D based on the gradient (direction of flow is determined by the positive or negative results of gradient calculation). Rich'816 does not disclose inserting the sensors into a gastrointestinal tract, or using pH sensors.

Kilcoyne'138 teaches a method of monitoring the flow in a gastrointestinal tract (paragraph [0003]) comprising using pH sensors (paragraph [0064]), in order to diagnose a patient's gastrointestinal reflux disease (GERD).

It would have been obvious to one of ordinary skill in the art at the time the method was made to have made the method of Rich'816 and performed it in a

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gastrointestinal tract using pH sensors, as taught by Kilcoyne'138, in order to diagnose the patient's GERD.

Regarding claim 38, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 37 above, except for immobilizing the sensors in the gastrointestinal tract. Kilcoyne'138 further teaches immobilizing the sensors in the gastrointestinal tract (paragraphs [0075]-[0088]), in order to ensure consistent measurement results.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Rich'816 in view of Kilcoyne'138, and immobilized the sensors in a GI tract, in order to ensure consistent measurement results.

Regarding claim 39, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 37 above, except for immobilizing the sensors in an esophagus. Kilcoyne'138 further teaches that the sensors may be immobilized in an esophagus (paragraphs [0075]-[0088]), in order to accurately diagnose GERD.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Rich'816 in view of Kilcoyne'138 and immobilized the sensors in an esophagus, in order to accurately diagnose GERD.

Regarding claim 41, Rich'816 further discloses transmitting the collected data to an external receiver (element 14; paragraphs [0049]-[0050]).

Regarding claim 42, Rich'816 further discloses processing the collected data in the sensor capsule and transmitting the results (that is, the flow direction determined from the gradient) to an external receiver (paragraphs [0070]-[0071]).

Regarding claim 43, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 37 above, except for diagnosing GERD based on output from the pH sensors. Kilcoyne'138 further discloses diagnosing GERD based on output from pH sensors (paragraphs [002]-[003]), in order to properly treat a patient.

Regarding claim 44, Rich'816 further discloses using the output of the sensors to determine flow velocity (paragraph [0083]).

Regarding claim 45, Rich'816 discloses a system for determining a direction of flow through a tract (paragraphs [0050] and [0083]), comprising first and second sensors (elements 12) configured to be inserted within the tract separated at a distance D (figure 19); and a processor configured to determine a direction of flow over the distance D based on a gradient between the output of the sensors over time (paragraphs [0071] and [0089]; direction of flow is determined by the positive or negative results of gradient calculation). Rich'816 does not disclose determining the flow in a gastrointestinal tract, or using pH sensors to determine the flow.

Kilcoyne'138 teaches a system for determining flow in a gastrointestinal tract (paragraph [0003]) using pH sensors (paragraph [0064]), in order to diagnose GERD.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Rich'816, configured it for insertion in a GI tract, and used pH sensors, as taught by Kilcoyne'138, in order to diagnose GERD.

Regarding claim 46, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 45 above, except for configuring the sensors for immobilization in an esophagus.

Kilcoyne'138 further teaches that the sensors are configured for immobilization in an esophagus (paragraphs [0075]-[0088]), in order to properly diagnose GERD.

Regarding claim 49, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 45 above, except for the pH sensors comprising ion selective field effect transistors (ISFETs). Kilcoyne'138 further teaches that the pH sensors may be ISFET (paragraph [0137]), in order to obtain a more accurate pH reading.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Rich'816 in view of Kilcoyne'138 and had the pH sensors comprise ISFETs, as taught by Kilcoyne'138, in order to obtain a more accurate pH reading.

Regarding claim 51, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 45 above, except for the system comprising a transmitter configured to transmit the output of the sensors to an external receiver. Rich'816 further discloses a transmitter (element 16) configured to transmit the output of the sensors to an external receiver (paragraphs [0049]-[0050] and [0071]).

3. Claims 40, 47, and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rich'816 in view of Kilcoyne'138, as applied to claim 37-39, 41-46, 49, and 51 above, and further in view of Merron'774 (US Patent Application Publication 2002/0109774).

Regarding claim 40, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 37 above, except for the sensors being within a swallowable capsule.

Merron'774 teaches a method of monitoring a GI tract comprising using a swallowable capsule with sensors, in order to make sensor insertion more comfortable for a patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the method of Rich'816 in view of Kilcoyne'138, and used a swallowable sensor capsule (paragraph [0035]), as taught by Merron'774, in order to make sensor insertion more comfortable for the patient.

Regarding claim 47, Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention, as applied to claim 45 above, except for the sensors being within a swallowable capsule.

Merron'774 teaches a GI monitoring system comprising a swallowable sensor capsule (paragraph [0035]), in order to make sensor insertion more comfortable for a patient.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Rich'816 in view of Kilcoyne'138, and used a swallowable sensor capsule, as taught by Merron'774, in order to makes sensor insertion more comfortable for the patient.

Regarding claim 48, Rich'816 in view of Kilcoyne'138 and Merron'774 discloses all the elements of the current invention, as applied to claim 47, except for the capsule comprising an image sensor. Merron'774 further discloses that the swallowable sensor capsule may comprise an image sensor (paragraphs [0009] and [0050]), in order to gain a more complete picture of the patient's GERD status.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Rich'816 in view of Kilcoyne'138 and Merron'774 and further had the swallowable sensor capsule comprise an image sensor, as taught by Merron'774, in order to gain a more complete picture of the patient's GERD status.

4. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rich'816 in view of Kilcoyne'138 as applied to claim 37-39, 41-46, 49, and 51 above, and further in view of Peterson'110 (US Patent 4200110).

Rich'816 in view of Kilcoyne'138 discloses all the elements of the current invention except for the pH sensors comprising pH sensitive color indicators. Peterson'110 teaches an implantable pH monitoring system comprising pH sensitive



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color indicators (column 1, lines 38-50), since it is well known in the art to monitor pH using color sensitive indicators.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Rich'816 and Kilcoyne'138, and used pH sensitive color indicators, as taught by Peterson'110, since it is well known in the art to monitor pH using color sensitive indicators.

### ***Response to Arguments***

5. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

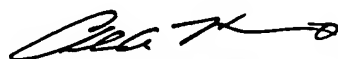
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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Charles A. Marmor, II  
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